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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,037	06/30/2005	Akinori Hanano	19036/40139	9381

4743 7590 06/20/2008

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EXAMINER	
VAKILI, ZOHREH	
ART UNIT	PAPER NUMBER
1614	

MAIL DATE	DELIVERY MODE
06/20/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/520,037	HANANO, AKINORI	
	Examiner	Art Unit	
	ZOHREH VAKILI	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 March 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 5-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 5-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The finality of the previous Office Action dated January 28, 2008 is hereby withdrawn.

Applicant's Amendment filed March 28, 2008 has been received and entered into the present application. Accordingly, claims 1, 5-11 are pending and are herein examined on the merits.

Applicant's arguments, filed March 28, 2008, have been fully considered. Rejections not reiterated from previous Office Actions are hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set of rejections presently being applied to the instant application.

Claim Rejections - 35 USC § 103 (New Grounds of Rejection)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, and 5-11 are rejected under 35 U.S.C. 103(a) as being unpatentable

over Trigg et al. (US Pub. No. 20050013784) in view of Murad (US Patent No. 6800292 B1) and further in view of Norton et al. (US Patent No. 5976556).

Trigg et al. teach in the present cosmetic useful vinyl polymers such as polyvinylpyrrolidone, polyvinyl alcohol, etc. (see paragraph 91). The Polyethylene glycol polymers useful herein are PEG-has an average value of about 2,000 an average value of about 14,000 (see paragraph 100). The pH of the present composition is preferably from about 4 to about 8. The pH may be adjusted to that which provides optimum efficacy of the active skin benefit agents. Buffers and other pH adjusting agents can be included to achieve the desirable pH. (see paragraph 106). The composition also includes glycolic acid (see paragraph 0126)

Murad teach the application that relates to dermatological agents for treating dermatological disorders (see abstract). Any suitable pharmaceutically acceptable carrier may be used with the dermatological agents, as will be readily apparent to one of ordinary skill in the art. Pharmaceutically acceptable carriers include, but are not limited to, hydroxypropyl cellulose, starch (corn, potato, rice, wheat), cellulose, polyethylene glycol and polyvinyl alcohol (col. 8, lines 37-65). Moisturizing agents that are acidic components include mono- or poly-hydroxy acids, tannic acid, and mixtures thereof. One of ordinary skill in the art would typically select one or more of the following mono- or poly-hydroxy acids: 2-hydroxyacetic acid (glycolic acid) (col. 9, lines 26-36). The acidic component, when present, is typically included in the composition and methods in an amount sufficient to exfoliate i.e., remove dead or dying skin cells,

from at least a portion of the skin (see col. 10, lines 22-25). A polymerization degree of from 2000 to 50000 is obvious of any polyethylene glycol in the preparation.

Norton et al. teach Novel compositions comprising one or more of an acid protease and an acidic buffer, the acidic buffer comprising an acid and a pharmaceutically or cosmetically acceptable carrier, vehicle or excipient, useful for treating or preventing abnormal biological conditions, diseases or disorders, and/or for improving the texture or appearance of the skin, and/or for enhancing epidermal exfoliation and/or for enhancing epidermal cell renewal and to methods for the use of the compositions. The acidic buffer comprises inorganic and/or organic acids or mixtures thereof with a pharmaceutically or cosmetically acceptable carrier, vehicle or excipient. The buffer is capable of reducing the pH of the surface of the skin to less than pH 5.5 and is susceptible to neutralization by normal epidermal processes. This invention relates to novel compositions comprising one or more of an acid protease enzyme and an acidic buffer, the acidic buffer comprising an acid and a pharmaceutically or cosmetically acceptable carrier, useful for treating or preventing abnormal skin conditions, diseases or disorders, and/or for improving the texture or appearance of the skin, and/or for enhancing epidermal exfoliation, and/or for enhancing epidermal cell renewal and to methods for the use of the compositions (see col. 1, lines 6-15). The acidic buffer is a composition which when topically applied to the skin, temporarily lowers the pH of the surface of the skin to less than about pH 5.5 but not lower than about pH 1.0, preferably to between about pH 2.5 and about pH 4.5. The acidic buffer composition comprises at least one acid and a pharmaceutically or

cosmetically acceptable carrier, vehicle or excipient. The acid component of the buffer can be an inorganic or an organic acid or mixtures thereof (see col. 4, lines 39-45). EXFOLIATION is defined as the detachment and shedding of superficial cells of an epithelium or from any tissue surface (see col. 7, lines 39-40). The acidic buffer is a composition which when topically applied to the skin, temporarily lowers the pH of the surface of the skin to less than about pH 5.5, but not lower than about pH 1.0, preferably about pH 2.5 to about pH 4.5. The acidic buffer composition comprises as least one acid and a pharmaceutically or cosmetically acceptable carrier, vehicle, or excipient (see col. 10, lines 8-11). The acid component of the acidic buffer of the composition can be an organic acid or an inorganic acid or mixtures thereof (see col. 10, lines 24-26). Examples of such acids include any molecule that can be manipulated in any composition to buffer the epidermal pH at pH ranges from about 0.1 to about 7 including, but are not limited to, lactic acid, sorbic acid, phosphoric acid, citric acid, **glycolic acid**, malic acid, gluconic acid, pyrophosphoric acid, triphosphoric acid, polyphosphoric acid, sodium bisulfate and potassium bisulfate. It should be understood that two or more acids can be used in combination such that the combined amount in weight percent is within the ranges mentioned above (see col. 10, lines 38-47). The acidic buffer also contains a component which is a pharmaceutically or cosmetically acceptable carrier, vehicle, or excipient. Examples of such pharmaceutically acceptable carriers, vehicles, or excipients are well known to

those skilled in the art (see col. 10 48-52). The compositions of the present invention intended for topical application may contain carrier, excipient, or vehicle ingredients such as, for example, water, acetone, ethanol, ethylene glycol, propylene glycol, butane-1,3-diol, isopropyl myristate, isopropyl palmitate, mineral oil, and mixtures thereof to form lotions, tinctures, creams, emulsions, gels, or ointments which are non-toxic and pharmaceutically, cosmetically, or dermatologically acceptable. Additionally, moisturizers or humectants can be added to the present compositions if desired (col. 10, lines 61-67 & col.11, lines 1-3). Methods of Use of the Compositions of the Present Invention: The present invention provides methods for enhancing epidermal exfoliation and/or for enhancing epidermal cell renewal. Such methods comprise topically administering to an area of a subject's skin an effective amount of a composition of the present invention, which comprises an acid protease enzyme exhibiting proteolytic activity below about pH 5.5 and insignificant activity at or above about pH 5.5 and an acidic buffer which lowers the pH of the surface of the skin to below about pH 5.5 for a period of time effective to enhance epidermal exfoliation and/or enhance epidermal cell renewal, the acidic buffer being subject to neutralization by natural epidermal processes (see col. 12, lines 8-19). The present invention also provides methods for improving the texture and/or appearance of skin. Such methods comprise administering to an area of a subject's skin an effective amount of a composition of the present invention, which comprises an acid protease enzyme exhibiting proteolytic activity below about pH 5.5 and insignificant activity at or above about pH 5.5 and an acidic buffer which lowers the pH of the surface of the skin to

below about pH 5.5 for a period of time effective to improve the texture and/or appearance of skin, the acidic buffer being subject to neutralization by natural epidermal processes (see col. 12, lines 20-31). A preferred method of administering an effective amount of a composition of the present invention for any of the methods described above on an area of skin is via topical application. The amount of the acidic buffer and acid protease in the final composition and frequency of topical application to the skin can vary widely, depending upon factors such as the particular skin disorder, the severity of the skin disorder, the location and/or type of the skin involved, the subject's skin sensitivity, and the degree of treatment desired. It is well within the purview of the skilled artisan to regulate dosages according to the subject's need (see col. 12, lines 62-67 & col. 13, lines 1-5). The composition according to claim 2 wherein the pharmaceutically or cosmetically acceptable carrier, vehicle or excipient component of the acidic buffer is selected from the group consisting of lotions, tinctures, creams, emulsions, gels, ointments, water, water-workable cream, **polyvinyl alcohol**, hydroxyethyl cellulose, cellulose, hydrophilic acrylic polymer, emollients, skin moisturizing components, enzyme stabilizers, glycerol, surfactants, preservatives, hydrophilic thickening agents used in pharmaceutical formulations and mixtures thereof (see col. 21, claim 3).

One skilled in the art would have been motivated to combine the teachings of the above references considering that it is generally prima facie obvious to combine two or more compositions each of which is taught by the prior art to be useful for the same

purpose, in order to form a composition which is to be used for the very same purpose. The idea for combining them flows logically from their having been used individually in the prior art. As shown by the recited teachings, the instant claims define nothing more than the concomitant use of PEG 2000 to 50000. It would follow that the recited claims define prima facie obvious subject matter. In re Kerhoven, 626 F.2d 848, 205 USPQ 1069 (CCPA 1980).

One would have been motivated to create such a composition comprising PEG 2000 to 50000 with a pH of 2.0. Therefore, one of ordinary skill in the art would have been motivated to use the above teachings and produce the composition comprising PEG 2000 to 50000 with a pH of 2.0, glycolic acid, and polyvinyl alcohol where each one of the components of the composition is taught by the above references.

Finally, one would have a reasonable expectation of success given that above mentioned references provide a detailed blueprint for a composition comprising PEG 2000 to 50000 with a pH of 2.0, glycolic acid, and polyvinyl alcohol and the steps of which are routine to one of ordinary skill in the art.

It would have been obvious given the motivation above to one of ordinary skill in the art, to have combined the teachings of the above references to produce a composition comprising PEG 2000 to 50000 with a pH of 2.0, glycolic acid, and polyvinyl alcohol. Each component of the formulation and its usage is taught in the references. As combined, the cited references result in the claimed invention.

Thus the claimed invention was within the ordinary skill in the art to make and use at the time the claimed invention was made and as a whole, prima facie obvious.

Applicant's remarks have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

No claims of the present application are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zohreh Vakili whose telephone number is 571-272-3099. The examiner can normally be reached on 9am to 6:00pm Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Examiner
Zohreh Vakili
Art Unit 1614

June 6, 2008

/Ardin Marschel/

Supervisory Patent Examiner, Art Unit 1614